UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

KAREN GREEN, Plaintiff, -against- COVIDIEN LP, Covidien.	Index No.: 1:18-cv-2939-PGG **SECOND AMENDED COMPLAINT AND JURY DEMAND**

Plaintiff, Karen Green, by her attorneys, MARC J. BERN & PARTNERS LLP, complaining of Covidien, upon information and belief, respectfully alleges as follows:

PARTIES

1. Plaintiff, Karen Green, is an individual and resident of the State of New York.

2. Plaintiff resides at 3 Curran Court Apt 3J, Yonkers, New York, 10710.

3. Defendant, Covidien LP ("Covidien"), is a Delaware Limited Partnership, headquartered at 15 Hampshire Street, Mansfield, Massachusetts 02048, with an additional place of business located at 480 Washington Boulevard, Jersey City, New Jersey 07310.

4. Covidien has registered an agent in the State of New York, and its agent is located at 111 8th Avenue, New York, New York 10011.

5. Covidien derives substantial revenue from sales directed at and occurring within the State of New York, including Symbotex™ Composite Mesh ("Product"), the subject of the present action.

6. Covidien is and has been at all times pertinent to this proceeding, engaged in the

design and manufacturing of medical technologies used by surgeons to treat a variety of conditions, including, but not limited to, hernia repairs. Covidien designed, manufactured, packaged, labeled, marketed, sold, and distributed the product at issue in this lawsuit.

JURISTICTION AND VENUE

7. This Court has personal jurisdiction over Covidien, pursuant to C.P.L.R.§302(a)(1), as nondomiciliary corporation transacting business, soliciting business, and deriving substantial revenue within the State of New York.

8. Jurisdiction is proper in this Court pursuant to C.P.L.R. § 302(a)(3) because a substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in New York. Specifically, Plaintiff is a New York resident, the Symbotex™ hernia mesh product (hereinafter "product" or "mesh product") was purchased in New York, the product was implanted in Plaintiff in New York, and Plaintiff's injury occurred in New York.

9. Further, jurisdiction is proper in this Court pursuant to C.P.L.R. § 302(a)(3), by virtue of the fact that Covidien's products are produced in, sold to, and implanted in individuals in the State of New York, including the Product, thereby subjecting Covidien to personal jurisdiction in this action. Plaintiff's claim arises from Covidien's presence and transactions in New York.

10. Covidien's activity with New York were purposeful and are substantially related to Plaintiff's injuries, which occurred in New York.

11. Covidien at all times relevant, regularly conducted and solicited, and continue to conduct and solicit, business in the State of New York through its agents, servants and employees, and because Covidien was engaged, and continues to engage, in marketing, distributing, promoting, and/or selling, either directly or indirectly, and/or through third parties or related entities, products, including but not limited to hernia mesh products, in New York.

12. Covidien at all times relevant engages, and continue to engage, in a persistent course

of conduct in the State of New York.

13. Covidien derives substantial revenue from goods used or consumed or services rendered in the State of New York.

14. Covidien expects or should reasonably expect its actions and course of conduct to have consequences in the State of New York and derive substantial revenue from interstate and/or international commerce.

15. Covidien actively sells, markets and promotes its hernia mesh products, including the product at issue here, to physicians and consumers in this state on a regular and consistent basis.

16. Covidien systematically availed itself of the State of New York by conducting regular and sustained business and engaging in substantial commerce and business activity in New York, including without limitation researching, developing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, processing, marketing, promoting, distributing, selling, and/or introducing into interstate commerce in the State of New York, either directly or indirectly, its products, including hernia mesh products, and the Product at issue. Covidien should expect that its acts would have consequences within the United States, and specifically, in the State of New York.

17. Plaintiff's claims arise from and relate to Covidien's purposeful availment of the State of New York because Covidien's wrongful conduct in researching, developing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, processing, marketing, promoting, distributing, selling, hernia mesh products, including the Product at issue, took place, in whole or in part, in the State of New York. Therefore, the claims of this New York resident Plaintiff relate to and arise from Covidien's explicit contacts and purposeful availment of the State of New York.

18. Venue is proper in this Court pursuant to C.P.L.R. § 503, because Plaintiff resides,

and has at all relevant times resided, in the State of New York, County of Westchester.

19. Venue is proper in this Court pursuant to C.P.L.R. § 503 because Covidien is a corporation authorized to transact business in the State of New York.

20. Venue is proper pursuant to C.P.L.R § 509.

FACTUAL BACKGROUND

I. HERNIAS, HERNIA MESH PRODUCTS, AND KNOWN ALTERNATIVES.

21. A hernia is a medical condition caused by the penetration of fatty tissue, intestine, or organs through a weakened or compromised location in muscle of connective tissue.

22. The most common types of hernias are: inguinal, hiatal, umbilical, ventral, incisional, and femoral hernias, most occurring near the abdominal wall.

23. Hernias sometimes manifest as visibly observable protrusions or bulges, and can cause the patient pain, discomfort, and decreased mobility.

24. Hernias can be treated surgically, either by laparoscopic or open repair surgical procedures.

25. Hernia repairs are common surgeries, and are performed more than one-million times per year in the U.S. Of all hernia repair surgeries, inguinal hernias account for approximately 80% of all hernia surgeries (an excess of 800,000 performed annually.)

26. The surgical mesh used to execute hernia repairs to damaged tissue can be constructed from synthetic or biologic materials and tissue. Synthetic surgical mesh is made of knitted or non-knitted sheets that can be absorbable, non-porous, or a combination of absorbable and nonabsorbent in composition.

27. Surgical mesh can be introduced to the hernia site to strengthen the repair in hopes of reducing the likelihood of recurrence.

28. Hernia mesh made from animal byproduct is usually derived from animal tissue sourced from skin or intestine and is designed to be absorbed into the human body upon use.

29. Non-absorbable mesh, made from synthetic materials, is intended to remain within the body permanently.

30. The most common injuries caused by hernia surgeries using synthetic hernia mesh are: pain, infection, adhesion of scar tissue sticking together, blockages that obstruct intestines, internal bleeding, fistula between organs (abnormal organ connection or fusion), serenoma or fluid build- up at site, and perforation of other organs.

31. Synthetic hernia mesh introduced to the body can cause serious injuries, including migration of the mesh and mesh shrinkage or contraction as well as the aforementioned conditions.

32. Additional defects and known side effects of synthetic hernia mesh, as used for reinforcement and strengthening of hernia repairs, include:

a. Synthetic mesh materials, as used, react to human tissues, organs and other body contents adversely.
b. Synthetic mesh materials can harbor or cultivate infections, which can affect surrounding areas, tissues, and organs.
c. Synthetic mesh material abrades bodily tissue, and can cause erosion of tissue and organs surrounding the placement of the mesh implant.
d. Mesh components routinely fail, malfunction or lose efficacy, resulting in serious adverse health implications, often requiring subsequent revision or removal surgery.
e. Synthetic mesh material causes significant injury, extending to perforation of surrounding tissue and/or organs, adhesion to other tissue and/or organs, and nerve damage.
f. Synthetic mesh material is intended to be rounded and reinforced to be safely cut, but when mesh is defective, it can become frayed, sharp, and protruding.
g. Unreasonable risk of malfunction, injury and health consequences, such as: severe chronic pain, infection, adhesion, intestinal blockages, migration of mesh, contraction/shrinkage of mesh, and requirement of repeat surgical intervention.

33. In April of 2016, the FDA wrote and published an article on synthetic hernia mesh

implants:

> Many complications related to hernia repair with surgical mesh that have been reported to the FDA have been associated with recalled mesh products that are no longer on the market. Pain, infection, recurrence, adhesion, obstruction, and perforation are the most common complications associated with recalled mesh.

34. Safer and more effective alternatives procedures to implanting synthetic hernia mesh, including the Product, exist and have existed since the introduction of hernia mesh products into the market. These include the Shouldice Repair, McVay Repair, Bassini Repair, and Desarda Repair. Moreover, the use of alternative materials instead of synthetic mesh, such as hemp and biologic materials and tissue including animal byproduct, are safer, feasible, and equally effective as synthetic mesh.

II. COVIDIEN'S PRODUCT – THE SYMBOTEX™ COMPOSITE MESH.

35. Covidien's Product – the Symbotex™ Composite Mesh (hereinafter "Symbotex™ Mesh") – was designed, patented, manufactured, labeled, packaged, marketed, sold, and distributed by Covidien at all relevant times herein. Covidien was responsible for the research, design, development, testing, manufacture, production, marketing, packaging, promotion, distribution, and sale of the product, as well as providing the warnings and instructions concerning the Product.

36. Among the intended purposes for which Covidien designed, manufactured, marketed, and sold the Product was for the use by surgeons for hernia repair surgeries- the purpose for which the Product was implanted in the Plaintiff, Karen Green.

37. Covidien's Product is designed, intended, and utilized for permanent implantation in the human body.

38. The Product is best used for laparoscopic and open ventral repair.

39. The Product is intended for permanent use to reinforce abdominal wall where soft tissue weakness exists.

40. The Product is advertised as having excellent tissue integration and minimized visceral attachments: "Symbotex™ Composite mesh is designed to match the surgeon's demands for ease of handling, operative efficiency, and versatility."

41. Covidien's online advertising material promotes the Product as having "Smart design," "Smart handling," and "Smart repair."[1]

42. Covidien's Product website provides its viewers with an animated video, "Explore the Enhanced Design," which is aimed to help an individual "discover the enhanced design" of the mesh and explains the material composition of the mesh and the technique that is used for implantation.

43. Covidien's Product website also provides its viewers with an animated video, "See Symbotex™ Mesh in Action," that shows the Product being implanted into a body, then adhering to the respective tissue.

44. Covidien's Value Analysis Committee Product Information Kit for Symbotex™ Composite Mesh for ventral hernia repair (hereinafter, "Product Brochure") represents that the Product "provides mesh transparency for improved anatomy visualization, easy mesh deployment, effective clinging for mesh placement, and excellent tissue integration for durable repair."[2] The Product Brochure states that the Product has "Exclusive 3-D mesh structure delivering reinforced textile strength and significant tissue ingrowth support."[3]

45. The Product Brochure further represents that the Product provides "Excellent tissue integration" and "Minimized visceral attachment."[4]

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[1] Medtronic Covidien Products Hernia Repair, *Symbotex™ Composite Mesh*, https://www.medtronic.com/covidien/en-us/products/hernia-repair/symbotex-composite-mesh.html (last visited September 20, 2019) (attached as **Exhibit 1**).
[2] Value Analysis Committee Product Information Kit for Symbotex™ Composite Mesh for ventral hernia repair, at page 4, https://www.medtronic.com/content/dam/covidien/library/us/en/product/hernia-repair/symbotex-composite-mesh-value-analysis-brochure.pdf (last visited September 20, 2019) (attached as **Exhibit 2**).
[3] *Id.* at page 5.
[4] *Id.* at pages 4, 6.

46. The Product is a surgical mesh material that is constructed of a three-dimensional monofilament macroporous polyester textile, which is covered with a bioabsorbable collagen film.

47. Polyester is a hydrophilic material as opposed to hydrophobic material such as polypropylene or polytetrafluoroethylene and thus encourages early biologic fixation and collagen ingrowth into surrounding tissue. Polyester has also been used as an implanted material in humans for decades in the form of vascular grafts with a good safety record.

48. Covidien represented to Plaintiff and Plaintiff's physicians that the Product was safe and effective for hernia repair and for permanent implantation in humans.

49. Covidien applied for U.S. Food and Drug Administration ("FDA") clearance to market the Product under Section 510(k) of the Medical Device Amendment.

50. Section 510(k) allows for the marketing of medical devices, so long as the medical device or material is deemed substantially equivalent to other legally marketed predicate devices or materials without predicate devices without formal review for the safety of efficacyof the device.

51. Covidien obtained clearance to market and sell the Product via 510(k) application, submitted on June 26, 2013, and approved by the FDA on August 22, 2013, as 510(k) No: K131969 4 for the use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.

52. To obtain FDA-approval to market and sell the Product, Covidien claimed the Product is substantially equivalent to the Parietex™ Composite Mesh as well as the Parietex™ Optimized Composite Mesh.

53. The FDA maintains an active compulsory database ("MAUDE DATABASE") of adverse incidents reported by medical providers regarding pharmaceutical implants and devices.

54. Every year, the FDA received hundreds of medical device reports ("MDRs") of suspected device-associated deaths, serious injuries, and malfunctions to contribute to the medical community's risk-benefit analysis of the use of certain devices.

55. MAUDE reports have been published documenting serious malfunctions of Covidien's Product.

56. Among the MAUDE reports are documented instances of adhesions of the small intestine adherent to the underside of the mesh and a tear in the mesh prior to the Product's implantation.

PLAINTIFF SPECIFIC FACTS

57. At all times relevant to this action, Plaintiff was and is a resident of New York.

58. On March 4, 2016, Plaintiff underwent a laparoscopic incisional hernia repair procedure performed by Jonathan Arad, M.D., to introduce Covidien's Product into Plaintiff's peritoneal cavity to reinforce tissue affected by the hernia.

59. The Product, manufactured and sold by Covidien, was used for Plaintiff's surgery. Specifically, a Symbotex™ Round Composite Mesh, 9cm diameter, REF No.: SYM9 and Lot No.: PPJ0516X, positively identified on surgical and operative reports prepared by Dr. Arad, was implanted into Plaintiff.

60. On or about March 13, 2016, Plaintiff underwent a subsequent surgery to explore complaints of abdominal pain, possible adhesions, partial small bowel obstruction and infected abdominal wall mesh.

61. During Plaintiff's March 13, 2016 surgery performed by Jonathan Arad, M.D., the Product was revised, and adhesions were taken down.

62. In addition to the surgery to revise the Product and take down adhesions, Plaintiff has experienced and continues to experience recurring hernias since the multiple procedures and the product implant. These injuries were not present before the implantation of the Product.

63. As a direct and proximate result of the Product that was implanted into her body, Plaintiff suffered, is suffering, and/or will continue to suffer the abovementioned injuries, including

the risk of malfunction, decreased efficacy, recurrent hernia, perforation of tissue and/or organs, adherence to tissue/organs, infection, nerve damage, subsequent surgeries, and other complications.

64. As a direct and proximate result of the wrongful acts and omissions of Covidien, Plaintiff has suffered economic damages, severe and possibly permanent injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this Product implanted in her body.

COUNT I : STRICT LIABILITY – DEFECTIVE DESIGN & MANUFACTURE

65. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

66. Covidien is a designer, manufacturer, marketer and distributor of hernia mesh products, including the Product.

67. Covidien is held to the standard of an expert in the field of hernia mesh product design, manufacture and marketing.

68. Covidien designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or introduce into the stream of commerce the Product.

69. Covidien had a duty to design, create, manufacture, market, distribute, and sell a product that was reasonably safe and not unreasonably dangerous for its normal, common, and intended use.

70. Covidien owed a duty to Plaintiff, Plaintiff's physicians, and others in the medical community, to exercise reasonable care in the design, manufacture, testing, marketing, and sale of the Product, and to provide adequate warnings with the Product.

71. Covidien breached that duty by designing and/or manufacturing the Product, which was not reasonably safe.

72. The Product was expected to, and did, reach Plaintiff and Plaintiff's healthcare providers with no substantial change in the condition in which the product was put into the stream of commerce by Covidien.

73. Plaintiff's healthcare providers used the Product for the purpose intended by Covidien, and in a manner normally intended for it to be used.

74. Covidien placed the Product into the stream of commerce with the actual or constructive knowledge that it would be used without inspection for defects.

75. Covidien placed the Product into the stream of commerce, which was defective and created an unreasonable risk of serious harm to the health, safety, and well-being of Plaintiff, Plaintiff's healthcare providers, and other consumers.

76. The Product's polyester fibers are constructed in a macroporous design which allows the Product's mesh to be stretched in different directions.

77. Polyester is a synthetic fiber derived from coal, air water, and petroleum.

78. Polyester is used chiefly to make synthetic textile fibers commonly found in clothing, home furnishings, and recording tapes.

79. Polyester degrades when implanted into the human body. Bodily degrading agents for polyester implantations can be physical (pulstaile force, high blood pressure), chemical (blood and physiological fluids), biological (thrombosis, infection), and thermal (body temperature: normal and elevated due to fever).

80. Polyester is prone to tearing, ripping, and/or fraying.

81. Once the polyester fibers unravel, they become detached from the mesh and migrate to other regions of the body.

82. These polyester fibers, once they become imbedded in different regions of the body, create an inflammatory response.

83. Polyester and collagen, respectively, are designed to work in concert to reinforce soft tissue and minimize tissue attachment to the Product in case of direct contact with internal organs.

84. The collagen film which coats the Product is designed to make the polyester material more tolerable to the body.

85. The collagen film in the Product, which was designed to make the polyester textile more tolerable to the body, is extremely delicate.

86. However, the collagen film in the Product fails to prevent the body's adverse reaction to the non-absorbable polyester mesh; once the delicate collagen barrier dissolves, internal organs are left unprotected from the dangers associated with the synthetic polyester textile.

87. Once the collagen barrier dissolves, it leaves the internal organs unprotected and increases the chances of adhesions, inflammatory response to the polyester, and formation of devastating scar tissue.

88. In addition to the polyester fibers unraveling, the mesh in the Product can also cause nerve damage.

89. Specifically, the macroporous design of the Product creates pores (holes) throughout the mesh used in it.

90. Nerves grow into the macro pores of the polyester textile after implant.

91. Polyester mesh contracts overtime, causing tension to increase where it is secured.

92. The stretching of the nerves causes debilitating pain. Additionally, this pain caused from the stretching of the nerves is essentially unable to be treated.

93. Nerves grow into these pores and attach to the mesh soon after implant.

94. As the Product's synthetic mesh erodes and moves through the inguinal canal, it pulls and stretches the nerves attached to it.

95. The nerves stretching causes debilitating pain that is essentially unable to be treated.

96. Moreover, polyester, the primary material used Covidien's Product is a synthetic non-absorbable textile known to cause adverse reactions in the human body.

97. Alternative designs for the Product existed that were and/or are less dangerous, equally effective if not more effective, and economically feasible and/or financially equivalent; these alternative designs for the Product include: the use of polycarbonate and polystyrene as alternatives to the Product's polyester; the use of a flat mesh and/or non-woven mesh instead of the polyester used in the Product; and the use of hemp or biologic materials including animal byproduct instead of the Product's polyester;

98. Hemp is a high-yield crop that grows very rapidly and with little irrigation (50% less than cotton), making it a very appealing and "clean" option.

99. Hemp is grown without the use of harmful chemicals, pesticides, herbicides or fertilizers, reducing the body's risk of adverse reaction to the material and reducing the chance of an inflammatory effect. It is also hypoallergenic, which reduces the chance of inflammation and adverse reactions, breathable, and UV resistant.

100. Alternative procedures also existed that were and/or are less dangerous and equally, it not more, effective that the use of the Product.

101. The Product was defective in design and formulation because, at the time it left Covidien's control and/or possession, it was in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use.

102. The Product was defective in design and formulation because, at the time it left Covidien's control and/or possession, the risks of harm – only foreseeable to Coviden – associated with the use of the Product exceeded the claimed benefits of the Product, and its utility did not outweigh the danger inherent in its introduction into the stream of commerce.

103. The Product was defective in design and formulation because, at the time it left

Covidien's control and/or possession, it contained an inherent flaw or error in its design that rendered it unreasonably dangerous.

104. The Product was defective in design and formulation because, at the time it left Covidien's control and/or possession, it was in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use.

105. The Product was defective in design and formulation because, at the time it left Covidien's control and/or possession, it contained latent or hidden dangers that could not have been known by Plaintiff of Plaintiff's healthcare providers nor discovered through use of reasonable care.

106. Covidien's Product left Covidien's hands in a condition not reasonably contemplated by the ultimate consumer and unreasonably dangerous for its intended use.

107. Alternatively, Covidien's Product failed to perform in its intended manner due to a flaw in the manufacturing process.

108. Due to an error in the manufacturing process, or through use of defective materials to manufacture the Product, the Product that was implanted in the Plaintiff deviated from the specifications or design of the Product.

109. The Product's deviation from its intended specifications and/or design failed to allow the Product to perform as intended and rendered the Product defective.

110. Covidien's Product was being used for the purpose and manner normally intended; specifically, hernia repair.

111. Because of defects in Covidien's Product, it is, and at all times material hereto was, unreasonably dangerous.

112. These defects existed when the Product was under the control of and distributed by Covidien.

113. Because of defects in Covidien's Product, it is, and at all times material hereto was, unreasonably dangerous.

114. Even through the exercise of reasonable care, Plaintiff and Plaintiffs physicians could not have discovered the defects in the Product and perceived its danger.

115. At the time of the defect, Covidien's Product was being used for the purpose and manner normally intended; specifically, hernia repair.

116. Even through the exercise of reasonable care, Plaintiff and Plaintiff's physicians could not have discovered the Product's defects or its perceived danger.

117. Plaintiff would not have been able to avert her injuries or damages caused by the defective Product through the exercise of reasonable care.

118. Plaintiff and Plaintiff's physicians were reasonably foreseeable users of Covidien's Product.

119. As a direct and proximate result of the defective and unreasonably dangerous design of the Product, it posed a substantial likelihood of harm to those who would be implanted with it, like the Plaintiff.

120. As a result of the Defendants failure to design and/or manufacture a reasonably safe Product, including but not limited to by using alternative materials or promoting alternative procedures, Plaintiff has suffered serious bodily injuries that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and interest on the foregoing injuries.

121. The foregoing losses and injuries are either permanent or continuing and Plaintiff will continue to suffer those losses in the future.

COUNT II: STRICT LIABILITY – FAILURE TO WARN

122. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set

forth herein.

123. The Product implanted in Plaintiff was defective and unreasonably dangerous when they left the possession of Covidien in that it contained warnings which were inadequate and insufficient to alert physicians or consumers to the dangerous risks associated with the Product, including, without limitation, extreme pain, risk of malfunction, decreased efficacy, recurrent hernia, perforation of tissue and/or organs, adherence to tissue/organs, infection, nerve damage, subsequent surgeries and other complications.

124. The Product's brochure, "Simply Smart," located on Covidien's webpage does not adequately address the reflect the nature of the injuries that can be sustained by the product's use, nor the severity of the injuries.[5]

125. Specifically, the last page of the Product's brochure, in fine print, refers its users including Plaintiff, Plaintiff's physicians, and others, to the package insert for complete instructions, contraindications, warnings and precautions. No warnings are provided or otherwise even mentioned in the Product's brochure.

126. The Product implanted in Plaintiff was defective and unreasonably dangerous when it left the possession of Covidien in that Covidien failed to include proper directions for use, implantation, and/or removal with the Product.

127. Specifically, Covidien failed to warn about injuries sustainable from the implantation of the Product, including but not limited to, mesh migration or "sliding" out of place, bowel incarceration, the need for removal surgery and the development of chronic pain syndrome, all of which Plaintiff has suffered.

128. The Product implanted in Plaintiff was defective and unreasonably dangerous when

[5] "Simply Smart" Symbotex Composite Mesh for ventral hernia repair, https://www.medtronic.com/content/dam/covidien/library/us/en/product/hernia-repair/symbotex-composite-mesh-brochure.pdf (last visited September 20, 2019) (attached as **Exhibit 3)**.

it left Covidien's control and possession because it failed to include proper directions for its use, implantation, and/or removal.

129. The warnings that were provided by Covidien regarding its Product were ambiguous, unclear, insufficient, and inaccurate.

130. Covidien's poorly-worded warnings provide:

> I. "The possible complications associated with the use of Symbotex™ Composite Mesh are those typically associated with surgically implanted mesh: seroma, hematoma, recurrence, fistula formation, adhesions, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product."

Exhibit 2 at page 11.

131. These warnings are a very generic and ineffective way to express that Covidien's Product has similar failures to other synthetic mesh products, which are not identified or described.

132. These "warnings" simply recite complications that are commonly associated with any foreign material implanted into the body and therefore are not specific for this Product.

133. At no time was Plaintiff warned of the "possible complication" that actually occurred, particularly that she would suffer a bowel obstruction, which has had lasting effects on her physical and mental well-being.

134. Covidien's Product implanted in Plaintiff was used for its intended purpose, *i.e.*, repair hernias through reinforcement.

135. Plaintiff's physicians, including the surgeons who implanted Covidien's Product into Plaintiff, could not have discovered any defect with the Product through the exercise of care.

136. Plaintiff's physicians, including the surgeons who performed the implant of Covidien's Product, did not have substantially the same knowledge that an adequate warning from its manufacturer or a distributor would have communicated.

137. Covidien owed a duty to Plaintiff and Plaintiff's physicians to communicate and provide a comprehensive briefing, in layman's terms and/or language that would have adequately apprised Plaintiff's physicians, informing the Product's users: what exactly was being implanted in her peritoneal cavity, including the exact material composition of the mesh; the Product's mesh had a lack of flexibility – known only by Covidien – and the risks of same (also only known by Covidien); how the Product's mesh was to be deployed and attached in the body; and the overall adverse reactions that the Product's foreign material could cause in her body.

138. Covidien owed a duty to warn Plaintiff and Plaintiff's physicians of all risks associated with the product, particularly the risks of bowel obstruction, adhesions which would require surgical intervention to repair, or deformation of the mesh.

139. Covidien had a continuing duty to warn Plaintiff and her doctors of the dangers associated with its hernia mesh products. As a direct and legal result of Covidien's failure to warn, Plaintiff has suffered serious bodily injuries, resulting in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, aggravation of a preexisting condition, and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT III – NEGLIGENCE

140. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

141. Covidien owed a duty to Plaintiff and Plaintiff's healthcare providers, and others similarly situated as foreseeable users of its Product, to manufacture and sell its Product in a reasonably safe manner for its intended use, free from defects.

142. Covidien owed a duty of care to Plaintiff and Plaintiff's healthcare providers, to

adequately warn against the risks associated with the foreseeable uses about hernia mesh products which Covidien knew or should have known, including but not limited to: the potential for perforation into human tissue; the potential to erode or "break down"; the potential to decrease in efficacy; the potential to cause patients observable abdominal bulging and pain many months after implantation; the potential for excessive scar tissue formation due to hernia mesh implantation, requiring future excision of scar tissue and lysis of adhesions; the potential for its hernia mesh products to overlie human tissue; muscle loss, weight gain, and/or continuous stomach pain associated with and/or caused by its hernia mesh products; loss of bowel function; increased diarrhea and stool related issues; and loss in mobility.

143.

144. Covidien breached its duty to Plaintiff and Plaintiff's healthcare providers by designing, manufacturing, and selling the hernia mesh products by, among other things, failing to properly fabricate the Product, failing to adequately test the Product, and failing to conduct adequate quality control procedures for the Product.

145. Covidien breached its duty by failing to adequately warn Plaintiff and/or her physicians of, *inter alia*, the aforementioned risks associated with the Product.

146. Any warnings that Covidien may have provided with its Product were inadequate and did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer and/or the medical community.

147. Covidien's failure to use reasonable care in the design, manufacture, and testing, and in the marketing and sale of the Product without provision of adequate warnings, directly caused Plaintiff's use of the Product and Plaintiff's injuries, which were a direct and proximate result of Covidien's negligence.

148. As a direct and proximate result of Covidien's breach of its duty of care, Plaintiff has

suffered serious bodily injuries that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, aggravation of a preexisting condition, and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT IV - BREACH OF WARRANTY

149. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

150. Covidien impliedly warranted to Plaintiff and all others similarly situated that its Product was reasonably fit for its intended use and that it was designed, manufactured, and sold in accordance with good design, engineering, and industry standards.

151. Covidien breached the above warranties because the Product was defective as set forth above, was not fit for its intended use and was not designed, manufactured, or sold in accordance with good design, engineering and industry standards.

152. As a direct and proximate result of Covidien's breach of its warranties pertaining to the Product, Plaintiff has suffered serious bodily injuries that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, aggravation of a preexisting condition, and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT V – FRAUDULENT MISREPRESENTATION

153. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

154. Covidien made misrepresentations of material fact from 2013 to present to Plaintiff and her physicians to induce them to use the Product for Plaintiff's hernia repair.

155. Covidien's webpage provides the public with a Product brochure (attached as Exhibit 3) that provides individuals with further information about the mesh implant, including biologic photographs and close-ups of the Product's mesh fibers.

156. Covidien's website also contains a "Value Analysis Committee Product Information Kit" (attached as Exhibit 2) for the public to download, informing readers of the Product's clinical studies, pertinent literature, product labels and comparable photographs.

157. The Product's "Value Analysis Committee Product Information Kit" also provides Product identification as well as the following statement: "Covidien's new Symbotex™ composite Mesh provides surgeons improved ease of use, and optimal performance to minimize visceral tissue attachments, for meeting hernia repair solution needs."

158. Covidien's webpage provides a link to a video showing the use of the Product in a hernia repair surgery.

159. Covidien's various advertisement materials lack detailed warnings about the known complications associated with the implantation of the Product, and the very limited warnings of potential complications associated with the Product were wholly inadequate.

160. Covidien made misrepresentations of material fact from 2013 to present, and in doing so omitted mention of crucial risks to Plaintiff and her physicians to induce them to use the Product for Plaintiff's hernia repair, including the following material facts known to Covidien:

a. Synthetic mesh materials, as used, react to human tissues, organs and other body contents adversely.
b. Synthetic mesh materials can harbor or cultivate infections, which can affect surrounding areas, tissue, and organs.
c. Synthetic mesh material abrades bodily tissue and can cause erosion of tissue and organs surrounding the placement of the mesh implant.
d. Synthetic mesh components routinely fail, malfunction or lose efficacy, resulting in serious adverse health implications, often requiring subsequent revision or removal surgery.
e. Synthetic mesh material causes significant injury, extending to

perforation of surrounding tissue and/or organs, adhesion to other tissue and/or organs, and nerve damage.

f. Synthetic mesh material is intended to be rounded and reinforced to be safely cut, but when mesh is defective, it can become frayed, sharp, and protruding.
g. Unreasonable risk of malfunction, injury and health consequences, such as: severe chronic pain, infection, adhesion, intestinal blockages, migration of mesh, contraction/shrinkage of synthetic mesh, and requirement of repeat surgical intervention.

161. Covidien made false and misleading representations of the risks of the Product in literature distributed to the medical community.

162. Covidien misrepresented material information regarding the Product by failing to disclose the known risks of its Product and predecessor devices.

163. Covidien intentionally, willfully, knowingly, and fraudulently misrepresented to the medical community, the FDA, and consumers, including the Plaintiff and her health care providers, that its Product had been adequately tested in clinical trials and was found to be safe and effective.

164. The information distributed by Covidien to the public, including the Plaintiff, the medical community, and the FDA, regarding the Product included, but was not limited to, reports, press releases, advertising campaigns, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth regarding the dangers of the use of Covidien's Product.

165. Product brochures are commonly used by medical device manufacturers and designers, such as Covidien, as advertisement material, and can be used by sellers such as Covidien to communicate terms of warranty to a buyer and can be a presumptive part of the agreement.

166. Covidien used its Product brochure to communicate terms of warranty and representations about its Product to its buyers, including but not limited to Plaintiff's physicians and/or medical providers.

167. Covidien's Product brochures do not provide detail about the potential complications

associated with its Product.

168. Plaintiff's health care providers and medical facilities relied on the misrepresentations by Covidien in its Product brochures and websites.

169. Covidien made continuous misrepresentations regarding the safety and efficiency of its Product to Plaintiff's medical providers and medical facilities through their website, as alleged throughout, and in other promotional materials distributed by Covidien to consumers.

170. Covidien's Product's "Mesh Value Analysis Brochure," attached as Exhibit 2, represents that the product "provides mesh transparency for improved anatomy visualization, easy mesh deployment, effective clinging for mesh placement, and excellent tissue integration for durable repair." This Product brochure also states that the product has "Exclusive 3-D mesh structure delivering reinforced textile strength and significant tissue ingrowth support."

171. The "Mesh Value Analysis Brochure," further states that the Product provides "Excellent tissue integration" and "Minimized visceral attachment."

172. The representations as to the ability of the Product's mesh to integrate with tissue are false because the Product's mesh actually had a poor rate of integration, evidenced by the Plaintiff's need for surgery due to improper adhesions, and the bowel obstruction she suffered.

173. Covidien, as a designer and manufacturer of pharmaceutical implant devices, had ample resources and sophistication, and actual knowledge of all risks of its Product.

174. Covidien engaged in commercial conduct by selling the Product.

175. Covidien knew at the time it made its misrepresentations and omissions pertaining to the Product that these representations were false.

176. Covidien intended that Plaintiff and her physicians would rely on its misrepresentations and omissions.

177. Given Covidien's ample resources and sophistication as designers and

manufacturers of pharmaceutical implant devices, Plaintiff, through her physicians and healthcare providers, and her physicians reasonably relied upon Covidien's misrepresentations and omissions regarding the safety and efficacy of Covidien's Product, resulting in the use of the Product which caused Plaintiff to sustain permanent personal injuries and damages.

178. In reliance upon Covidien's false and fraudulent misrepresentations, through her physicians and healthcare providers, the Plaintiff and her physicians were induced to, and did, reasonably rely upon Covidien's misrepresentations and omissions regarding the safety and efficacy of Covidien's Product, resulting in Plaintiff sustaining permanent personal injuries and damages.

179. Covidien had sole access to material facts concerning the defective nature of its Product and its propensity to cause serious and dangerous injuries and damages to persons who used its Product.

180. Covidien had sole access to material facts concerning the defective nature of the Product and its propensities to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Product.

181. Covidien knew, and had reason to know, that its Product could cause serious personal injury to those who received an implant, and that its Product were inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings given.

182. Covidien made its fraudulent misrepresentations and omissions pertaining to its Product intentionally, willfully, wantonly, and with reckless disregarded and depraved indifference for the safety and well-being of the users of its product, including Plaintiff.

183. Covidien's wrongful conduct was fraudulent, deceitful, committed and perpetrated willfully, wantonly, and purposefully.

184. Covidien's fraudulent misrepresentations and omissions were made with the intent

of defrauding and deceiving the medical community and the public, including Plaintiff, and to induce the medical community to recommend, dispense and purchase Covidien's Product.

185. As a foreseeable, direct, and proximate result of Covidien's described misrepresentations and omissions, Plaintiff suffered the serious and dangerous side effects more specifically described in this Complaint.

186. As a direct and proximate consequence of Covidien's fraudulent misrepresentations, Plaintiff sustained serious personal injuries and related losses including mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, medical and related expenses, and other losses and damages.

COUNT VI – NEGLIGENT MISREPRESENTATION

187. Plaintiff incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

188. Covidien had a duty to represent truthfully and accurately to the medical community, the FDA, and United States consumers accurately and truthfully, including Plaintiff, the results of Covidien's Product testing. The misrepresentations made by Covidien was false; Covidien was careless or negligent in ascertaining the truth of the representations at the time Covidien made the misrepresentations.

189. Covidien represented and marketed its Product as being safe and effective.

190. After Covidien became aware of the risks of its Product, Covidien failed to accurately communicate those risks associated with its Product.

191. Covidien failed to exercise ordinary care in the representation concerning its Product and its manufacture, sale, testing, quality assurance, quality control, and distribution. Covidien negligently and/or carelessly misrepresented and intentionally concealed the truth regarding the high risk of the Product's unreasonable, dangerous, and adverse side effects associated with the

administration, use, and implantation of the Product.

192. Covidien breached its duty in representing to the Plaintiff, its physicians and healthcare providers, and the medical community as a whole, that its Product did not carry the risk of serious side effects such as those suffered by Plaintiff and other similarly situated patients

193. Plaintiff, and her healthcare providers, physicians, and surgeons justifiably relied on Covidien negligent misrepresentations.

194. As a direct and proximate consequence of Covidien negligent misrepresentations, Plaintiff sustained serious personal injuries, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical and related expenses, and other losses and damages.

COUNT VII- UNJUST ENRICHMENT

195. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

196. Covidien is, and at all times were, the manufacturer, seller, supplier, distributor, marketer, and/or dealer of the Product.

197. Plaintiffs paid for Covidien's Product for the purpose of effective and safe hernia repair.

198. Covidien has accepted payment by Plaintiff for the purchase of its Product, and was, therefor, unjustly enriched.

199. Covidien fiscally benefited through its receipt of payment from Plaintiff for the purchase of the Product.

200. Covidien's enrichment was obtained at the expense of Plaintiff's financial, physical and mental wellbeing.

201. Plaintiff has not received the safe and effective Product for the hernia repair for which

she paid.

202. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

COUNT VIII - VIOLATIONS OF GBL §349 and §350

203. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

204. Covidien acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including Plaintiff herein and Plaintiff's physicians and medical providers, rely upon such concealment, suppression and omission, in connection with sale, advertisement and promotion of its Product.

205. Covidien, in violation of all applicable state consumer fraud statutes, made fraudulent representations for the purpose of influencing and inducing physicians and medical providers to implant Covidien's Product (specifically the Symbotex™ Composite Mesh) to patients/consumers such as the Plaintiff herein. Because of Covidien's unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff herein, were caused to suffer ascertainable loss of money and property and actual damages.

206. Covidien engaged in consumer-oriented, commercial conduct by selling and advertising the Product.

207. Covidien misrepresented and omitted material information regarding the Product product by failing to disclose known risks.

208. Covidien's represents, through a "Mesh Value Analysis Brochure," (attached as Exhibit 2) that the Product "provides mesh transparency for improved anatomy visualization, easy

mesh deployment, effective clinging for mesh placement, and excellent tissue integration for durable repair." This Product brochure also states that the product has "Exclusive 3-D mesh structure delivering reinforced textile strength and significant tissue ingrowth support."

209. The "Mesh Value Analysis Brochure," further represents that the Product provides "Excellent tissue integration" and "Minimized visceral attachment."

210. The representations as to the ability of the Product's mesh to integrate with tissue are false, as the Product's mesh had poor integration, evidenced by the Plaintiff's need for surgery due to improper adhesions, and the bowel obstruction she suffered.

211. Covidien's misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the Product, in violation of New York General Business Law ("GBL") §§ 349 and 350.

212. New York has enacted statutes to protect consumers from deceptive, fraudulent and unconscionable trade and business practices. Covidien violated these statutes by knowingly and falsely representing that the Product was fit to be used for the purpose for which it was intended, when Covidien knew said Product was defective and dangerous, and by other acts alleged herein.

213. Covidien engaged in the deceptive acts and practices alleged herein in order to sell the Product to the public, including Plaintiff.

214. As a direct and proximate result of Covidien's violations of GBL §349 and §350, Plaintiff suffered damages, for which Plaintiff are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

215. As a direct and proximate result of Covidien's conduct, the Plaintiff used and/or had the Product and suffered serious physical injury, harm, and damages as a result.

216. Covidien's action and omission as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

217. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such Covidien is liable pursuant to the exceptions set forth in Article 16 of the C.P.L.R.

218. Pursuant to C.P.L.R Section 1602(2)(iv), Covidien is jointly and severally liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of C.P.L.R. Section 1601, by reason of the fact that Covidien owed Plaintiff a non-delegable duty of care.

219. Pursuant to C.P.L.R. Section 1602(2)(iv), Covidien is liable for all of Plaintiff damages, including but not limited to, Plaintiff non-economic loss, irrespective of the provisions of C.P.L.R. Section 1601, by reason of the fact that said Covidien is vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

220. Pursuant to C.P.L.R. Section 1602(7), Covidien is jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of C.P.L.R. Section 1601, by reason of the fact that said Covidien acted with reckless disregard for the safety of others.

221. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

COUNT IX – PUNITIVE DAMAGES

222. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

223. Covidien sold its Product to the healthcare providers of the Plaintiff and other healthcare providers in the state of Plaintiff's implantation (New York) and throughout the United

States without doing adequate testing to ensure that its Product was reasonably safe for implantation in the pelvic area.

224. Covidien sold the Product to the Plaintiff's health care providers and other health care providers in the state of the implantation (New York) and throughout the United States despite its knowledge that its Product can disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this complaint, thereby causing severe and debilitating injuries suffered by Plaintiff and numerous other patients.

225. Covidien ignored reports from patients and health care providers throughout the United States and elsewhere of its Product's failures to perform as intended, which lead to the severe and debilitating injuries suffered by Plaintiff and numerous other patients. Rather than doing adequate testing to determine the cause of these injuries, or to rule out its Product's design or the processes by which its Product is manufactured as the cause of these injuries, Covidien chose instead to continue to market and sell its Product as safe and effective.

226. Covidien knew its Product was unreasonably dangerous in light of its risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of its Product, as well as other severe and personal injuries which were permanent and lasting in nature.

227. Covidien withheld material information from the medical community and the public in general, including the Plaintiff, regarding the safety and efficacy of its Product.

228. Covidien knew and recklessly disregarded the fact that its Product caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods, designs, materials, and/or products used to treat hernias.

229. Covidien misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by its Product.

230. Notwithstanding the foregoing, Covidien continues to aggressively market the Product to consumers, without disclosing the true risks associated with its Product.

231. Covidien knew of its Product's defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the Product so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff.

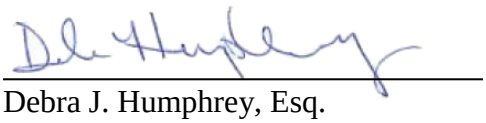
232. Covidien continues to conceal and/or fail to disclose to the public, including the Plaintiff, the serious complications associated with the use of its Product to ensure continued and increased sales of the Product.

233. Covidien's conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Covidien herein in an amount that exceeds the jurisdictional limitations of all lower courts that would otherwise have jurisdiction over this action, together with the interest, costs and disbursements of same allowed by law.

Dated: New York, New York
September 20, 2019

MARC J. BERN &PARTNERS LLP
Attorneys for Plaintiff



Debra J. Humphrey, Esq.

CERTIFICATE OF SERVICE

I certify that on September 23, 2019, I filed the foregoing Second Amended Complaint with the Clerk of this Court by using its electronic filing system, which will send notice of this filing to all counsel of record.

/s/ Debra J. Humphrey
Debra J. Humphrey
Attorneys for Plaintiff